

REMARKS

After entry of this amendment, claims 11-17, 19-21, 23, 25, and 27-29 are pending. Claims 1-10, 22, 24, and 26 are cancelled without prejudice or disclaimer. The claims have been amended without prejudice or disclaimer to better comply with U.S. practice and for proper dependency. Support for the amendments is found *inter alia* in the original claims. New claim 29 finds support in the specification at page 12, lines 2-4. No new matter has been added.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 26-28 were rejected under 35 USC § 112, second paragraph, as being indefinite for reciting “at least one additive.” Applicants strongly disagree.

As stated in § 2173.02 of the M.P.E.P. “[t]he test for definiteness under 35 U.S.C. 112, second paragraph, is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’” (M.P.E.P. § 2173.02, emphasis added). If one skilled in the art is able to ascertain the meaning of the terms in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. See M.P.E.P. § 2173.02. Furthermore, the specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in context in the specification. It is entirely proper to use a specification to interpret what the patentee meant by a word or phrase in the claim. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc); and *Vitronics Corp. v. Conceptor Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The meaning of “at least one additive” is provided in the specification at page 11, lines 5-34. Accordingly, Applicants respectfully submit that the claims are clear when read in view of the specification, and therefore, satisfy the requirements under 35 USC § 112, second paragraph.

Reconsideration and withdrawal of this rejection is respectfully requested. Claim 26 was cancelled without prejudice or disclaimer, thus the rejection as to claim 26 is rendered moot.

Rejections under 35 U.S.C. § 102

Good et al.

The Examiner rejects claims 11-14, 17, 19-23, 25, 27 and 28 under 35 U.S.C. 102(b) as being anticipated by Good *et al.* (U.S. Patent 4,689,297; hereinafter "Good"). Applicants respectfully disagree and traverse the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference." *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir. 1997).

The Examiner alleges that Good discloses a method of preparing a pelletized enzyme-containing particle by coating a hydratable core-particle with an enzyme and then a film-forming macro-molecular material and concludes that the preamble of claim 11 is met because a particle that contains an enzyme is formed. Applicants respectfully disagree with the Examiner's characterization of Good as it relates to the instant claims. The only disclosure in Good referring to a pelletized granule is "bentonite/kaolin/diatomaceous earth disk pelletized granules" as an example of a possible core particle which is subsequently coated with an enzyme (see col. 3, lines 13-20). In contrast, claim 11 recites that the method comprises pelletizing a mixture of feed constituents and an enzyme-containing granulate suitable for use in animal feed which comprises a mixture of at least one enzyme, a solid support suitable for feedstuffs and water. Thus the pelletizing of the instant claims is conducted with a granulate already containing an enzyme before the pelletizing step, in contrast to Good where the enzyme is subsequently coated onto a core or pellet. Thus Good does not disclose a method of preparing a pelletized enzyme-containing particle as alleged by the Examiner.

Moreover, claim 17 recites a pelleted feedstuff composition. Good does not disclose or mention feedstuff or pelleted feedstuff.

Because Good does not teach or disclose pelletizing an enzyme-containing granulate, feed constituents, feedstuff, or pelleted feedstuff, Good does not teach or disclose all the limitations of the claims and as such cannot anticipate the claims.

The Examiner alleges that the claims do not specify the nature of the structure of the granulate. Applicants respectfully disagree. The claims recite that the enzyme-containing granulate comprises a mixture of at least one enzyme, a solid support suitable for feedstuffs and water.

The Examiner additionally asserted that the burden has shifted to Applicants to show that the Good granulates do not inherently possess the feature of a pelleting stability greater than an uncoated granulate. For a rejection based on inherency to be proper, the Examiner must provide rationale or evidence tending to show inherency. *See* MPEP § 2112(IV). This requirement that rationale or evidence be provided by the Examiner *is separate and in addition to* the requirement that the Examiner base the rejection on a reference that teaches a product appearing to be substantially identical to the claimed product. *See* MPEP 2112(V). In addition, for the Examiner to establish inherency, the rationale or evidence provided "must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference." *In re Robertson*, 169 F.3d 743, 745 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The rationale provided by the Examiner is based on the method of Good and the granulate produced therefrom allegedly meeting the claimed methods steps and resulting structure of the instant claims, an enzyme-containing particle coated by a polymer. However, the Examiner has failed to show that Good discloses *pelletizing* a mixture comprising a granulate already containing an enzyme. Additionally, the Examiner has failed to show that Good discloses feedstuff or pelleted feedstuff comprising a granulate already comprising an enzyme. Moreover, the Examiner in making the inherency rejection asserted one would "reasonably expected" that the granulates would have the same pelleting characteristics. The standard requires that the missing descriptive matter *necessarily be present*. Good discloses that particle temperatures were below 50° C (see Good at col. 4, lines 56-57) and in the examples Good showed product temperatures of 45° C (see Example 5 at col. 7, line 66), 34-38° C (see Example 5 at col. 8, line 4), and 37-41° C (see Example 5 at col. 8, line 11). Good does not disclose pelletizing a mixture comprising a

granulate already containing an enzyme or that the particles could withstand temperatures during a pelletizing step, for example temperatures in the range of about 60° to 100° C (see specification at page 12, lines 2-4). Thus, the Examiner has not provided the required rationale or evidence that the Good methods or granulates inherently possess a pelleting stability greater than an uncoated granulate. The Examiner therefore has not made clear that the pelleting stability is *necessarily present* in the Good granulates. As such, the Examiner's alternative inherency-based anticipation rejections of claims 11, 17, and 22 were improper. As such, the burden remains with the Examiner to present rationale or evidence that the granulates of Good inherently possess a pelleting stability greater than an uncoated granulate. For this additional reason, Good does not anticipate the claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Thoma et al.

The Examiner rejects claims 1-4, 6, 7, 8, 11, 12-14, 17, and 19-28 under 35 U.S.C. 102(b) as being anticipated by Thoma *et al.* (1999; hereinafter "Thoma"). Applicants respectfully disagree and traverse the rejection.

The Examiner asserts that Thoma discloses the stability of polymer coatings on the stability of enteric coated pellets and tablets. The Examiner also asserts that the pellets were coated with various polymers. As with Good, the pellets described in Thoma are used as a core which are subsequently coated. Thus, Thoma, as with Good, discloses that with using a pellet as a core, any *pelletizing would have occurred before the coating* with a polymer. In contrast, the claims recite that the method comprises pelletizing a mixture of feed constituents and an enzyme-containing granulate suitable for use in animal feed which comprises a mixture of at least one enzyme, a solid support suitable for feedstuffs and water wherein the granulate is already coated before the pelletizing step. Thus, the pelletizing of the instant claims *would have occurred after the coating* of the polymer in order to achieve greater pelleting stability than an uncoated granulate. Therefore Thoma does not teach or disclose pelletizing an enzyme-containing granulate which is already coated as recited in the claims, rather Thoma teaches

coating a pellet core. Because Thoma does not teach or disclose all the limitations of the claims, Thoma does not anticipate the claims.

The Examiner asserts that Thoma provides analysis of well known enteric coating polymers and their stability. Enteric coatings are designed for gastric resistance, *i.e.* to withstand acid conditions, low pH (see Thoma, page 40, left col., line 16, right col., section 2.6). However, the present application relates to improving stability during pelletizing, thus being able to withstand high temperatures (see specification page 12, lines 2-4). Being able to withstand low *pH* as disclosed in Thoma is a totally different requirement than being able to withstand the high *temperatures* to which the granulates would be exposed to during pelletizing in the present application. In further contrast to the present application, Thoma teaches that the enzyme can be damaged by humidity and heat during coating (See for example, Thoma, abstract line 9).

The Examiner additionally asserted that the burden has shifted to Applicants to show that the Thoma granulates do not inherently possess the feature of a pelleting stability greater than an uncoated granulate. As explained above under Good, for a rejection based on inherency to be proper, the Examiner must provide rationale or evidence tending to show inherency. *See* MPEP § 2112(IV). This requirement that rationale or evidence be provided by the Examiner *is separate and in addition to* the requirement that the Examiner base the rejection on a reference that teaches a product appearing to be substantially identical to the claimed product. *See* MPEP 2112(V). In addition, for the Examiner to establish inherency, the rationale or evidence provided "must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference." *In re Robertson*, 169 F.3d 743, 745 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). As such, inherency may not be established by probabilities or possibilities and the mere fact that a certain thing *may result* from a given set of circumstances is not sufficient. *Id.* *See also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). The rationale provided by the Examiner is based on the method of Thoma and the granulate produced therefrom allegedly meeting the claimed methods steps and resulting structure of the instant claims, an enzyme-containing particle coated by a polymer. However, the Examiner has failed to show that Thoma discloses *pelletizing* a mixture comprising a coated granulate containing an enzyme where the pelletizing *occurs after coating* in order to achieve greater pelleting stability than an uncoated granulate as

required by the claims. Moreover, the Examiner in making the inherency rejection asserted one would “reasonably expected” that the granulates would have the same pelleting characteristics. The standard requires that the missing descriptive matter ***necessarily be present***. Thoma teaches that the enzyme can be damaged by humidity and heat during coating (See for example, Thoma, abstract line 9). Thoma does not disclose pelletizing a mixture comprising a coated enzyme-containing granulate or that the particles could withstand the high temperatures during a pelletizing step, for example temperatures in the range of about 60° to 100° C (see specification at page 12, lines 2-4). Thus, the Examiner has not provided the required rationale or evidence that the Thoma methods or granulates inherently possess a pelleting stability greater than an uncoated granulate. The Examiner therefore has not made clear that the pelleting stability is ***necessarily present*** in the Thoma granulates. As such, the Examiner’s alternative inherency-based anticipation rejections of claims 1, 11, 17, and 22 were improper. As such, the burden remains with the Examiner to present rationale or evidence that the granulates of Thoma inherently possess a pelleting stability greater than an uncoated granulate. For this additional reason, Thoma does not anticipate the claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Itoh et al. in view of Good or Thoma

Claims 1-4, 6, 7, 9-12, 16, 17, and 19-28 are rejected as being obvious under 35 U.S.C. § 103(a) over Itoh *et al.* (U.S. Patent No. 5,080,917, hereinafter “Itoh”) in view of Good or Thoma. Applicants respectfully disagree and traverse the rejection.

To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner characterizes Itoh as disclosing a method of making coated granules for animal feed and granules thereof which allegedly meets the limitations of claims 1, 11, 17, 22, and 25. Applicants strongly disagree.

Itoh does not mention, teach or suggest *pelletizing* nor pelleting stability as required by the claims. Itoh does not teach or suggest that an organic-polymer coating would improve the pelleting stability of an enzyme-containing granulate compared to an uncoated granulate. Furthermore, the Examiner has previously acknowledged that Itoh does not teach a pellet comprising a polymer-coated enzyme-containing granule (see Office Action mailed January 26, 2007 at page 5). Good and Thoma do not remedy this deficiency. As explained above, neither Good nor Thoma disclose *pelletizing* a coated enzyme-containing granulate as required by the claims. Rather Good and Thoma teach coating a core which may be a pellet, where any pelletizing would have occurred *before* the coating. Thoma and Good do not teach pelletizing *after* coating of a granulate already containing an enzyme. Thus Itoh, Good and/or Thoma, alone or in combination, do not teach all the claim limitations as required to establish *prima facie* obviousness.

The Examiner further asserts that Good and Thoma are drawn to using polymers to serve as coatings on enzyme-containing cores to protect the enzyme from the acid environment. The coating of the Itoh granules also serves to protect the granules from acidic degradation in the stomach of the animal. Thus, all three references cited by the Examiner disclose granules that are able to withstand acid, *i.e.* low pH. In contrast the present application requires that the coated granules are able to withstand the conditions during pelletizing, for example high temperatures, temperatures in the range of about 60° to 100° C (see specification at page 12, lines 2-4). Thus, an enzyme-containing granulate which is pelleted after coating as required by the claims would have to be able to withstand the conditions of pelleting. One of ordinary skill in the art of pelleting would know that during pelletizing process temperatures are high as also described in the specification at page 12, lines 2-4. Making granules to withstand low pH as taught by the references cited by the Examiner does not teach or suggest making granulates that can withstand a pelletizing step where the granulates are exposed to high temperatures.

The Examiner concludes that it would be obvious that the organic-polymer coated enzyme-containing granulates would have had a pelleting stability greater than an uncoated enzyme-containing granule. The Examiner based the conclusion on the specification allegedly not providing a specific definition for "pelleting stability" and interpreting this term to mean

stability of the pellet in any type of situation. Applicants strongly disagree with the Examiner's conclusions and standard used.

First, the Examiner cites to *In re Zeltz*, stating that "[t]his means that the words of the claim must be given their plain and ordinary meaning unless applicant has provided a clear definition in the specification." *In re Zeltz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Nowhere in *In re Zeltz* is such a statement found and the holding does not stand for this proposition. Rather the court in *In re Zeltz* in the context of an indefiniteness rejection under 35 U.S.C. § 112, paragraph second, found that the Board had erred by reading limitations into the claims that were contrary to the plain words of the claims and contrary to the interpretation that the inventor himself placed on the claims. Rather the Federal Circuit held that "[d]uring patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." The court further held that "the inquiry during examination is patentability of the invention as 'the applicant regards' it."

Second, it is entirely proper to use a specification to interpret what the patentee meant by a word or phrase in the claim. But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By "extraneous," the United States Court of Appeals for the Federal Circuit defines limitations into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). The claims require a pelletizing step, a pelleted composition, or that the pelleting stability be greater than an uncoated granulate. The terms "pelletizing," "pelleted" and "pelleting stability" are already in the claims and are not being added to the claims. Contrary to the Examiner's interpretation of *In re Zeltz*, the specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in context in the specification. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc); and

Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). Contrary to the Examiner's assertion, the specification can be used to interpret a claim term without an explicit definition. The term "pelletizing stability" recited in the claims is defined in the present specification by implication according to the usage of the term in the specification (see for example, specification at page 11 line 40 through page 12 line 5, and Experiment 1 at page 20-21), which is different than reading a limitation from the specification into the claims. See *Phillips*, 415 F.3d at 1321. The Examiner also stated that "'pelletizing stability' is interpreted to mean the ability of the active substance in the coated granulate to maintain its activity *after pelletizing* of the granulate." Even using this interpretation, there still must be *pelletizing* of the granulate. None of the references cited by the Examiner teach or suggest pelletizing a coated enzyme-containing granulate. None of the references cited by the Examiner teach or suggest that such a pelletized composition has a pelletizing stability greater than an uncoated granulate.

The Examiner additionally interpreted "pelletizing stability" to mean stability of the pellet in any type of situation. The Examiner argues that Itoh performs the same process as the instant claims to make enzyme-containing granulates that are coated and demonstrates that the coating is responsible for preserving the amino acid activity. The Examiner further alleges that the ordinary artisan would be motivated by the disclosure of the polymers of Good which are allegedly drawn to the same purpose for coating granules in the instant invention to protect enzymes from the acid environment of the stomach and during storage (see Office Action pages 10-11). Applicants strongly disagree with the Examiner's interpretation and conclusions. The claims and the specification describe stability as it relates to *pelletizing* a coated enzyme-containing granulate. As explained above, the granules disclosed in Itoh, Good, and/or Thoma relate to withstanding acid conditions in a stomach, *i.e.* low pH. In contrast the present application requires that the coated granules are able to withstand the conditions encountered during pelletizing, *i.e.* high temperatures, which are well known to one of ordinary skill in the art (see for example references cited in specification at page 1; also see Barendse *et al.* (U.S. Patent 6,500,426), already of record, for example at col. 1, lines 46-59, and Table 1 at col. 12) and described, for example, in the specification, with temperatures in the range of about 60° to 100° C (see specification at page 12, lines 2-4). Thus, the purpose of the coating of the present application and those of the references cited by the Examiner are totally different and unrelated.

Additionally, the Examiner appears to have combined the references based on the purpose of the coatings allegedly being the same as the instant application. Contrary to the Examiner's assertion, as just explained, the purposes for coating are totally different between the references cited by the Examiner and that of the instant application. The motivation provided by the Examiner is unrelated to the present application. Moreover, one of ordinary skill in the art would not look to a reference or references disclosing coated granules capable of withstanding *low pH* in a stomach for granules capable of withstanding conditions during *pelletizing*, for example *high temperatures*. Further, since none of the references cited by the Examiner teach or suggest pelletizing or pelleting stability, no expectation of success is provided by any of the references. (A reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. See MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). For these additional reasons, Itoh, Good and/or Thoma, alone or in combination, do not render the claims obvious.

As explained, the coatings of the Itoh, Good and/or Thoma granules serve to protect the granules from acidic degradation in the stomach of the animal, which is different than withstanding the conditions of pelletizing of high temperatures. As found by the court in *In re Antonie*, which reversed the Board's finding of obviousness, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. § 103. *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977); see also MPEP § 2141.02 V. Furthermore, the court in *In re Antonie* found that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness. *Id.* Similarly here, Itoh, Good and/or Thoma, alone or in combination, do not disclose or suggest pelletizing a coated enzyme-containing granule or improved pelleting stability of an organic-polymer coated enzyme-containing granule.

Moreover, it is well established that under 35 U.S.C. § 103 the Examiner must consider the reference as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Being able to withstand low pH rather than being able to withstand the conditions during pelletizing, *i.e.* high temperatures, are totally different requirements. Furthermore, Thoma, for example, teaches that the enzyme can be damaged by humidity and

heat during coating (See Thoma, abstract line 9). This teaches away from being able to withstand the conditions during pelletizing, for example high temperatures, as in the instant application.

Because none of the references cited by the Examiner, alone or in combination, teach or suggest pelletizing a coated enzyme-containing granule, improved pelleting stability of an organic-polymer coated enzyme-containing granule, or pelleted granules that would withstand the conditions during pelletizing, Itoh, Good and/or Thoma, alone or in combination, do not render obvious the subject matter of independent claims 11 or 17 or the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Reconsideration and withdrawal of this rejection is respectfully requested. Claims 1-10, 22, 24, and 26 are cancelled without prejudice or disclaimer, and as such the rejections relating to these claims are moot.

Itoh et al. in view of Good or Thoma in further view of De Lima et al.

Claims 1-4, 6, 7, 9-17, and 19-28 are rejected as being obvious under 35 U.S.C. § 103(a) over Itoh in view of Good or Thoma, in further view of De Lima *et al.* (U.S. Patent No. 6,136,772, hereinafter "De Lima"). Applicants respectfully disagree and traverse the rejection.

To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. *See In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner relies on De Lima for teaching a granule that contains phytase. The Examiner asserts that De Lima teaches coated enzyme-containing granules and alleges that the product of De Lima can be used for animal feed or detergent.

However, the teaching of a granule containing phytase does not remedy the lack of teaching in Itoh, Good and/or Thoma.

The explanations provided above for Itoh, Good and/or Thoma are equally applicable to this rejection and are incorporated herein in their entirety.

The Examiner alleged that it would be obvious to make the coated phytase-containing granulate as taught by the combined references. The Examiner further alleged that one of ordinary skill in the art would be motivated to do so because it was recognized by De Lima and Itoh that stabilization of biologically active substances by coating granules containing the same is important to long term stability, especially feeds. Applicants respectfully disagree with the Examiner's interpretation and conclusions.

"[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). Furthermore, the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990); 16 *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992). Thus, it is impermissible to simply engage in a hindsight reconstruction of the claimed invention where the reference itself provides no teaching as to why the applicant's combination would have been obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). A reasonable expectation of success must be established for a proposed combination of references to render claims *prima facie* obvious. See MPEP § 2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)). The teaching or suggestion to make the combination and the reasonable expectation of success must both be found in the prior art. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

As acknowledged by the Examiner, Itoh does not teach an enzyme-containing granulate suitable for animal feed (see Office Action, page 8). As explained above, Itoh does not teach or suggest pelletizing, improved pelleting stability, or pelleted granules. Rather Itoh teaches

granules that are capable of withstanding acid conditions in a stomach, *i.e.* low pH. Good and/or Thoma do not remedy this lack of teaching of Itoh as explained above. The stabilization mentioned in Itoh is related to stability in the stomach of a ruminant, thus capable of withstanding stomach acid, *i.e.* low pH. The Examiner has provided no explanation relating to stability as it applies to De Lima. The Examiner refers to De Lima as teaching a coating comprising polyethylene glycol (PEG); however, when the reference is read as whole, the context of the disclosure of this coating only applies to detergent granules and is not related to applications of granules generally (col. 17; see also Decision on Appeal, already of record). In De Lima, in the examples which refer to feed enzymes (Examples 26 and 27), granules are coated with melted hydrogenated palm oil not PEG (see col. 36, line 29). Thus the examples of De Lima direct one skilled in the art to using oil for coating feed granules and not organic polymers as recited in the instant claims or the coatings taught by Itoh for withstanding low pH.

Since Itoh does not teach or suggest enzyme-containing granulates suitable for animal feed (as acknowledged by the Examiner) and only teaches granules as they relate to stability in low pH, Itoh provides no motivation to combine the teachings of De Lima relating to feed enzymes and oil coatings. Furthermore, Itoh describes the disadvantages of using coating agents that comprise triglycerides, hydrogenated fats originating from plants, waxes and mixtures thereof in its process (see Itoh, col. 1, lines 33-38). Thus, Itoh teaches away from the combination with De Lima. The Examiner alleges that De Lima discloses that other coatings are available and suitable for all enzyme/starch granulates, but has not provided any support for such a statement. Thus, the motivation provided by the Examiner of long term stability is not supported by the references cited nor the explanation provided, and further is not relevant to the instant claims relating to pelletizing and pelleting stability. The Examiner has further not provided any explanation why De Lima would be combinable with Itoh and Good and/or Thoma. The Examiner has thus failed to articulate a sufficient reason or rationale for combining the teachings of De Lima with the combined teachings of Itoh and Good or Thoma, as proposed by the Examiner, in a manner that encompasses the instant claims. Because Itoh teaches away from the combination with De Lima and no motivation or insufficient explanations for the combination have been provided, the references are not properly combinable and do not render obvious the present application.

Assuming *arguendo* the references were combinable, the Examiner has not provided any basis for modifying the granule taught by Itoh with that of De Lima to arrive at the instant claims. The Examiner asserts only that the method of making the coated granulate by the combined references is a design alternative that is similar to the method of De Lima. However, making the coated granulates as asserted by the Examiner is not a mere design alternative, since Itoh describes the disadvantages of using coating agents similar to the coating used in De Lima.

As explained in detail above, Itoh, Good and/or Thoma, alone or in combination, do not teach or suggest pelletizing a mixture comprising a enzyme-containing granule coated with an organic polymer, improved pelleting stability of an organic-polymer coated enzyme-containing granule, or pelleted granules that would withstand the conditions during pelletizing as recited in the claims. De Lima relied on for teaching phytase granules does not remedy this deficiency as just explained.

Because none of the references cited by the Examiner teach or suggest all the claim limitations, because De Lima is not properly combinable with Itoh, Good and/or Thoma, and because the Examiner has not provided adequate explanations for the combination to establish *prima facie* obviousness, the references cited by the Examiner, alone or in combination, do not render obvious the instant claims. Reconsideration and withdrawal of this rejection is respectfully requested.


CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a one-month extension of time, to and including March 31, 2008 pursuant to 37 CFR § 1.7(a), to respond to the Office Action mailed November 29, 2007 with the required fee authorization. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account

No. 03-2775, under Order No. 13111-00039-US from which the undersigned is authorized to draw.

Respectfully submitted,

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